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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/707,983	01/29/2004	Edward M. Gillis	DUR-021130	1982
22876	7590	06/13/2006	EXAMINER	
FACTOR & LAKE, LTD 1327 W. WASHINGTON BLVD. SUITE 5G/H CHICAGO, IL 60607			SMITH, PAUL B	
		ART UNIT	PAPER NUMBER	
			3763	

DATE MAILED: 06/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/707,983	GILLIS ET AL.
	Examiner Paul B. Smith	Art Unit 3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 29 January 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-19 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-19 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 29 January 2004 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application, from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/3/2006
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 3/3/2006 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner considers the references cited therein.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the medical insertion device must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

3. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an

application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the examiner does not accept the changes, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 19 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The medical insertion device claimed is not described in the specification and there is no drawing detailing the structure.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Bonutti *et al.* ('730).

8. Bonutti *et al.* discloses an expandable device comprising a cannula shaft (10), a puncture tip (72), at least one rigid element (16), and a flexible material (18). (See Figures 6-9) The rigid element is taught to compose of metal. (See Column 3 Lines 53-60) The flexible material is taught to be an elastomeric plastic. (See Column 4 Lines 15-21) The device is taught to be used with a stylet (70). (See Figure 16)

9. Thus, Bonutti *et al.* appear to reasonably teach every element of claims 1-14.

10. Claim 19 is rejected under 35 U.S.C. 102(b) as being anticipated by Klein *et al.* ('553).

11. Klein *et al.* discloses a medical insertion device comprising a delivery shell (12), a channel (18), a nose (14), a withdrawal mechanism (not referenced), and a handle (16). (See Figure 1)

12. Thus, it appears that Klein *et al.* reasonably teaches every element of claim 19.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bonutti *et al.* ('730) in view of Dibelius ('883).

16. Bonutti *et al.* discloses an expandable device comprising a cannula shaft (10), a puncture tip (72), at least one rigid element (16), and a flexible material (18). (See Figures 6-9) The rigid element is taught to compose of metal. (See Column 3 Lines 53-60) The flexible material is taught to be an elastomeric plastic. (See Column 4 Lines 15-21) The device is taught to be used with a stylet (70). (See Figure 16)

17. Bonutti *et al.* fails to disclose a cannula comprising a rigid element in a helix shape.

18. Dibelius teaches embedding a fine wire molded double helix embedded in a flexible material. (See Column 1 Lines 45-50)

19. It would have been obvious at the time of the invention to one of ordinary skill in the art to modify the disclosure of Bonutti *et al.* with the structural teaches of Dibelius to provide an expandable cannula with rigid elements in a helix shape.

20. Claim 16 rejected under 35 U.S.C. 103(a) as being unpatentable over Bonutti *et al.* ('730) in view of Kim *et al.* ('852).

21. Bonutti *et al.* discloses an expandable device comprising a cannula shaft (10), a puncture tip (72), at least one rigid element (16), and a flexible material (18). (See Figures 6-9) The rigid element is taught to compose of metal. (See Column 3 Lines 53-60) The flexible material is taught to be an elastomeric plastic. (See Column 4 Lines 15-21) The device is taught to be used with a stylet (70). (See Figure 16)

22. Bonutti *et al.* fails to teach a rotating cannula having a first and a second rigid element that comprise a portion of a cylinder arc.

23. Kim *et al.* ('852) disclose an expandable device that comprises a first and a second rigid element that are concentric to a center line of the device such that the second rigid element is capable of rotating around the center line. (See Figure 3 and 4)

24. Thus it would have been obvious at the time of the invention to one of ordinary skill in the art to modify the expandable device of Bonutti *et al.* with the teachings of Kim *et al.* ('852) to provide an expandable device that expands by rotating a first and second rigid element that comprise a portion of a cylinder arc.

25. Claim 17 rejected under 35 U.S.C. 103(a) as being unpatentable over Bonutti *et al.* ('730) in view of Kim *et al.* ('318).

26. Bonutti *et al.* discloses an expandable device comprising a cannula shaft (10), a puncture tip (72), at least one rigid element (16), and a flexible material (18). (See Figures 6-9) The rigid element is taught to compose of metal. (See Column 3 Lines 53-60) The flexible material is taught to be an elastomeric plastic. (See Column 4 Lines 15-21) The device is taught to be used with a stylet (70). (See Figure 16)

27. Bonutti *et al.* fails to teach a cannula comprising a ribbon spring that is at least one rigid element formed in the shape of a helix and having a center channel.

28. Kim *et al.* ('318) teaches an expandable device comprising a rigid element in the shape of a helix and having a central channel. (See Figure 7)

29. Thus it would have been obvious to one of ordinary skill in the art at the time of the invention to provide an expandable cannula comprising a ribbon spring by modifying the disclosure of Bonutti *et al.* with the teachings of Kim *et al.* ('318).

30. Claim 18 rejected under 35 U.S.C. 103(a) as being unpatentable over Gill *et al.* ('729).

31. Bonutti *et al.* discloses an expandable device comprising a cannula shaft (10), a puncture tip (72), at least one rigid element (16), and a flexible material (18). (See Figures 6-9) The rigid element is taught to compose of metal. (See Column 3 Lines 53-60) The flexible material is taught to be an elastomeric plastic. (See Column 4 Lines 15-21) The device is taught to be used with a stylet (70). (See Figure 16)

32. Bonutti *et al.* fails to teach a cannula comprising a rolled rigid material having a first and second longitudinal side such that overlapping the first and second longitudinal side allows the diameter to be varied.

33. Gill *et al.* discloses an expandable cannula comprising a single rigid sheet that is rolled such that one side overlaps the other thus resulting in a variable diameter. (See Figure 3 and 4)

34. Thus it would have been obvious at the time of the invention to one of ordinary skill in the art to modify the disclosure of Bonutti *et al.* with the teachings of Gill *et al.* in order to provide an expandable cannula comprising a rigid sheet that can be rolled to form a variable diameter cannula.

Conclusion

35. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- a. U.S. Patent 2,566,499 to Richter
- b. U.S. Patent 6,942,684 to Bonutti
- c. U.S. Patent 6,814,715 to Bonutti *et al.*

36. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul B. Smith whose telephone number is 571-272-6022. The examiner can normally be reached on 8 am - 4 pm.

37. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

38. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul B Smith
Examiner
Art Unit 3763

PBS
May 30, 2006



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